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Memo to File - Interview with Arleen Auerbach - May 6, 1988

Dr. Auerbach came to see me -- her possibility of doing that having been opened up by my prior conversation with Rodman Rockefeller on whom I had urged the categorical necessity of having the institutions involved^{be}, both with respect to IRB and with respect to proprietary problems.

Dr. A. has no contractual relationship with the firm, whose principal is Ted Boyce at the Memorial Hospital and in which RR is a venture capital investor. Their concept is the use of cells derived from cord blood as a fruitful source of progenitor stem cells for grafts into individuals with marrow defect, like the aplastic anemia of Fanconi's Disease (which is how Dr. A. comes into the picture.) Fanconi patients have an unexplained loss of stem cells and there have been a number of efforts to sustain them with marrow transplants. The best results have been achieved at the Hospital St. Louis in Paris where they have now achieved something like 70% survival rates. There are very delicate questions of achieving cytoreduction that involve very careful adjustment of the dose of cyclophosphamide, since Fanconi cells are much more sensitive than others. (I had a question whether cytoreduction was necessary at all in Fanconi's Disease but that has never been directly tested.) It is not just the marrow cells but the other rapidly proliferating cells in the body in the Fanconi patients that complicate the cytoreduction preparation.

Other protocols at Memorial ^{Hospital} have had disastrous results and so they have abandoned marrow transplant for Fanconi for sometime. They have never followed the French protocol.

Ted Boyce's company is devoted to various applications of fetal (cord blood cells) which they would bank for later use. In some cases this would be for autologous transplantation. The Fanconi's is one good candidate for a transplant of cord blood cells from siblings. Apparently a number of Fanconi patients have been clam~~m~~oring about that possibility and there are one and two cases ready to go to clinical trial.

A Dr. Gordon Douglas at NYU, former chief of their Ob-Gyn Dept^t, appears to be a principal in the RR firm and has been doing the actual collection of the cord blood. Dr. A's role has been to do the diagnosis of Fanconi syndrome in cells received from other places.

I reassured her that, while her obligation to keep the matter a secret was inevitably uncomfortable, that things had not proceeded to any point of real difficulty as far as I could determine; and that she should rest easy that her conduct was irreproachable up to this point.

I outlined the necessity of connecting any involvement that she might have ^{first} with IRB approval, and then attending to what the University's proprietary rights might be. I spelled out that whatever she did in the course of her work at the University was University property and she could not get additional compensation for that. On the other hand, her general advice about

their strategy for development of the therapy for the conduct of clinical trials, and so on, was outside of her University duties (and furthermore would have distinct social benefit) and so I would not discourage her from being a consultant on that basis. If on the other hand she does provide access to patients or materials, that come out of her work on Fanconi here, then the University had certain rights and those would have to be considered. Dr. A. mentioned that she had proposed to RR that the University receive funds for the laboratory in order to continue certain testing but that was not approved ^{by him} at that time. I responded that my conversation with RR ^{ne} opened the possibility of a closer relationship involving the University but we would have to think about that very carefully.

Next steps: Dr. A. will consult with her lab chief Dr. Carter as she is now free to do. If access to patients or patient materials are involved, Dr. Kappas will have to be informed; and of course he would be involved in any IRB surveillance of what they do.

My own judgement (which Dr. A. is not in disagreement with) is that the more crucial questions have to do with the rather poor results that have been achieved so far with cytoreduction except in Paris. But there, the 70% survival represents a standard of outcome that would be very difficult for competing therapies to match. But these are questions that the IRB's can go into. In the present cases there might be some preference to having used cord blood cells from recently born siblings of

Fanconi patients. ^{otherwise,} since (one would ~~not~~ have to go to them for sources of marrow, which would also involve some delay and some discomfort to the young child, although that probably would be approved in order to save the life of a sibling.) So there are complex ethical issues here about whose rights are in question.